K113541

510(k) Summary

DEC 16 2011

Company address and contact:

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Contact: David Gustafson, Vice President, Research and Development
Date Prepared: October 21, 2011

1. Identification of the Device

Proprietary Trade Name: ClearStart·SVM™, Segmentation and Volumetric Measurement (SVM)
Classification Name: System, Image Processing, Radiological
Common/Usual Name: System, Image Processing Radiological
Product Code: LLZ

2. Equivalent Legally Marketed Device:

Manufacturer: Siemens Medical Solutions, USA, Inc.
Name of Predicate Device: *syngo* CT Oncology
FDA 510(k) Number: K071310
FDA Clearance Date: June 8, 2007.

3. Indications for Use Statement

The **INTIO ClearStart•SVM™** system is a self-contained image analysis desktop workstation addressing the needs of physicians performing diagnostic oncologic imaging, treatment planning, and post-procedure or systemic therapy follow-up assessment. ClearStart•SVM™ provides semi-automated tools for segmentation of suspicious lesions including primary and metastatic lung and liver tumors, and lymph node assessment using non-contrast and contrast CT images. Following lesion segmentation, ClearStart•SVM™'s automated volumetric, RECIST and WHO lesion measurements provide the user with data on the time-course of patient response to therapy. An on-board large disk storage capacity allows the user to easily track each patient's CT data from initial diagnosis through therapeutic interventions and follow up exams and includes a reporting package to aid in the assessment of response to therapy.

The system is password protected so that only the above mentioned trained medical professionals are authorized users.

4. Description of Device

The ClearStart•SVM™ product consists of a custom-configured desktop computer system consisting of high-performance commercial-off-the–shelf computer components, and INTIO proprietary software running on a Linux operating system. CT data is read into the system from a CD or DVD and stored uncompressed into a database which allows easy retrieval for follow up assessments.

The ClearStart•SVM™ system uses data from contrast and non-contrast CT examinations of patients presenting with solid tumors. SVM segments the tumor within the organ and determines measurements such as longest tumor length in axial views and tumor volume. Diagnostic CT scans are viewed in both multiplanar reformatted (MPR) views and 3D volume rendered (VR) views, allowing the user to choose the best visualization of selected tumors to be treated. Typically tumors are best visualized in the contrast CT exam which is used for analysis. User selected lesions are segmented with minimal user input. The user places a cursor over the tumor and by clicking a mouse button inserts one or more region-growing seed points in the tumor to be segmented.[1] Feedback of the seed location is shown in graphical overlays on the MPR views. After the seed or seeds are placed, the user activates a computer determined bounding box surrounding the marked lesion, with the surrounding tissue demonstrating a contrast difference to the marked tumor. The lesion is then segmented using 3D active contour methodology[2].

As a follow up to a specific therapy the ClearStart•SVM™ system provides tools to help assess the effectiveness of image-guided loco-regional or systemic therapies for solid or semi-solid tumors throughout the body. Users are able to review changes in tumor dimensions based on follow up CT scans with computer-assisted segmentation and automated measurement of lesions to determine tumor response to therapy over time. The ClearStart•SVM system is designed to semi-automatically segment and automatically measure tumors of the liver, lung, and lymph nodes.

INTIO engineers have developed ClearStart•SVM™'s image processing and display software which provides both 2D (MPR) image display and 3D volume-rendered (VR) display capability. Response of tumors to therapy, either loco-regional or systemic, is facilitated by lesion segmentation and automated measurement leveraging INTIO's proprietary image segmentation algorithm. The automated measurements include both conventional and specific quantitative measurements such as RECIST, WHO and volumetric CT measurements.

5. Comparison to Predicate Device

A predicate product, *syngo* CT Oncology from Siemens Medical Solutions, is our substantially equivalent product for comparison. The main features of the INTIO ClearStart•SVM™ and Siemens CT Oncology products are shown in Table 5-1. There is nearly a complete feature set match between the ClearStart•SVM™ and CT Oncology systems. Siemens references "automated" tumor segmentation, but since their system requires some user inputs it more correctly should be called semi-automated

[1] Adams R and Bishof L, Seeded Region Growing, IEEE Trans PAMI (1994) 16(6): 641-647.
[2] Zhang L et al., Segmentation of liver tumors in CT scans using a 3D active contour method. Int J CARS (2010) 5 (Suppl 1): S287

segmentation. Similarly, the INTIO ClearStart•SVM™ product is a user initiated semi-automated segmentation process wherein the user identifies the target lesion to be assessed and uses a computer mouse to graphically mark one or more areas in the lesion. From that point onward all the processing is automated. Both products provide summary information for reports which the users may utilize in their assessment of the response to various cancer therapies.

Table 5.1 Feature Comparison to Predicate Device

INTIO ClearStart•SVM™ Feature	**Siemens CT Oncology Feature from 510(k) K071310 Summary**
Semi- automated and Automated tools from CT data for:	Automated tools from CT data for:
Segmentation (semi-automated)	Automated Segmentation
Automated Volumetric Assessment of Lesions	Automated Volumetric Assessment of Lesions
Specifically for: Liver Lung Lymph nodes	Specific tools for: Liver Lung and Lymph nodes
Reporting of results for time serial tumor response assessment	Reporting of results to track lesions over time
Indications for use: The **INTIO ClearStart•SVM™** system is a self-contained image analysis desktop workstation addressing the needs of physicians performing diagnostic oncologic imaging, treatment planning, and post-procedure or systemic therapy follow-up assessment. ClearStart•SVM™ provides semi-automated tools for segmentation of suspicious lesions including primary and metastatic lung and liver tumors, and lymph node assessment using non-contrast and contrast CT images. Following lesion segmentation, ClearStart•SVM™'s automated volumetric, RECIST and WHO lesion measurements provide the user with data on the time-course of patient response to therapy. An on-board large disk storage capacity allows the user to easily track each patient's CT data from initial diagnosis through therapeutic interventions and follow up exams and includes a reporting package to aid in the assessment of response to therapy	Indications for use: ***syngo* CT Oncology** is a self-contained, non invasive image analysis software package designed to fast-track routine diagnostic oncology, staging and follow-up. Flexible layouts and automated image registration facilitate the synchronous display and navigation of multiple datasets for viewing multi-phase CT data and easy follow-up comparison. The application provides a range of automated tools specifically designed to support physicians in the segmentation and volumetric evaluation of suspicious lesions including dedicated tools for lung, liver and lymph node assessment in CT data. Dedicated workflow-support and integrated, accumulative reporting allow to track lesions and their changes in e.g. size, shape and enhancement pattern over time. Syngo CT Oncology also facilitates functional imaging offering fusion with other modalities such as PET data. It also features syngo LungCAD for detecting small lung nodules (PMA-approved).

Hardware/Software Platform: Built Linux operating system, AMD PC Platform	Hardware Software Platform: Built on syngo common software, Intel/Windows PC Platform.
User Interface: Graphical user interface for control of all system features.	User Interface: Graphical user interface for control of all system features

6. Testing Information and Conclusion

In all material aspects, INTIO ClearStart•SVM is substantially equivalent to the predicate system, both being built on PC platforms using a windowed user interface environment. Both internal and third party testing was performed to assure that the system is safe and efficacious prior to use by customers. INTIO's Test Engineering Department performed software verification testing considering an array of test use cases following internal test procedures to assure that the system design specifications were realized. Medical professionals who are familiar with similar systems validated the software workflow and usability confirming that the system's design intent was realized. Together with these validation and verification processes we engaged a third party electronics testing laboratory (ETL) to assure compliance to appropriate regulatory standards for electromagnetic compatibility and electrical safety. When we receive 510(k) clearance the software and hardware will be formally released to production by an ISO 13485 compliant third party manufacturing partner.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

INTIO Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

DEC 16 2011

Re: K113541
Trade/Device Name: ClearStart·SVM™, Segmentation and Volumetric Measurement
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 30, 2011
Received: December 1, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): _____

Device Name: ClearStart·SVM™, Segmentation and Volumetric Measurement

Indications for Use:

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Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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